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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,943	01/24/2001	Chandler R. Dawson	03654.0250.CNUS02	2773

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EXAMINER

PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 04/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 45-102 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 45-102 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

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In view of the Preliminary amendments which have not been considered, the Office Action of March 13, 2002 is hereby withdrawn and an action on the merits of all the claims in the case is given herein below.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-60, 70-87 and 95-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No.

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6,239,113 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods are encompassed by the patented methods.

Claims 45, 47-60, 70-81, 83-87 and 95-96 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of eye infections, does not reasonably provide enablement for prevention of eye infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The terminology “prevent” reads on treating a healthy eye i.e. for delivering a vaccine to an eye for which there is no support in the specification.

Claims 47-48, 61-69, 83-84, 88-94 and 97-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is improper to use the term “comprises” (claims 47-48 and 83-84) with respect to a compound because it leaves the structural formula of the compound open-ended.

Claims 61-69 and claims 88-94 are substantial duplicates.

Claims 97-98 and claims 99-100 are substantial duplicates.

Note that a composition, whether administered to a human or a non-human, is the same composition.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45-51, 71--72, 83--87 and 95-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Dawson (First Meeting of the WHO alliance for the Global elimination of Trachoma, Geneva, 30 June - July 1997).

Dawson discloses the claimed method of topically treating an eye infection with an azalide antibiotic.

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Claims 61-69, 88-94 and 97-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over the International Patent No. WO 95/09601 or Curatolo et al (U.S. Patent No. 5,605,889).

Each of The International Patent (page 5) and Curatolo et al (column 8, lines 20-45) discloses suspensions of azithromycin and polymeric suspending agent but do not disclose the specific amounts encompassed by the claims. However, since it would have been prima facie obvious to a person having ordinary skill in the art at the time the instant invention was made to vary the amounts of azithromycin and the polymer, the claimed compositions are deemed prima facie obvious over the art of record. Further, ta person having ordinary skill in the art at the time the instant invention was made would have been motivated to combine two known antibiotics into a single composition because such a person would have expected the resulting composition to be useful as an antibiotic.

Claims 65-66 and 88-89 are rejected under 35 U.S.C. 102(b) as being anticipated by Bright (U.S. Patent No. 4,474,768).

Bright discloses a composition comprising azithromycin and an ophthalmically acceptable carrier, such as water (column 7, lines 23-32).

Claims 45-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al (U.S. Patent No. 5,192,535) in view of Bright (U.S. Patent No. 4,474,768).

Davis et al disclose ophthalmic suspensions for topical administration containing erythromycin (column 9, line 14) but do not disclose said suspensions containing azithromycin.

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However, since azithromycin is a derivative of erythromycin as disclosed by Bright, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to substitute azithromycin for erythromycin in a composition disclosed by Davies et al because the results obtained by such a substitution would have been expected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peslev whose telephone number is (703) 308-4616. The examiner can normally be reached on weekdays from 8.30 a.m. to 5.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached on (703) 308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

elli peslev
ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200